

## REMARKS

### **I. Rejections or Objections to Claims in the Office Action**

The Office Action mailed April 21, 2004 rejects or objects to claims on the following bases:

- (1) Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120;
- (2) Claims 1-4, 6, 8-18, 22-26, 28, 30-35, 37, and 39-50 were rejected under 35 U.S.C. 102(b) as being anticipated by Vierra et al. 5,749,892;
- (3) Claims 5, 27 and 36 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Furnish et al. 5,498,256;
- (4) Claims 7, 29 and 38 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Garrison et al. 5,613,937; and
- (5) Claims 19-21 were rejected under U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of in view of Hossain et al. 6,063,021.

Each of the foregoing rejections is responded to below, where each response references the number corresponding to each rejection set forth above.

### **II. Response to Rejections Made in the Office Action**

- (1) Applicant has complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120.

The Office Action mailed April 21, 2004 noted that the specification states that it is a cip of 09/493,466, which is a divisional of 08/531,363. It was pointed out that 09/493,466 is not copending with 08/531,363. The Examiner is respectfully thanked for the careful review of this application. The Office Action stated, "The Examiner further notes that the current claims are drawn to the embodiment of figures 34-45. None of the prior cases support his subject matter. Hence, the current claims have only the current filing date, or 10/2/2000, even if the priority claim were corrected." Applicants respectfully disagree. Applicants respectfully submit that at least some of the claims are supported by the earlier disclosures. As an example of support, and

not intended to limit the claims in any fashion, applicants note Figure 25 and the original text describing that Figure as one example, among others.

A petition in accordance with 37 CFR 1.78(a)(3) and the surcharge set forth in 37 CFR 1.17(t) are submitted to correct the priority claim. The corrected priority claim now states “This application is a continuation-in-part application claiming priority from U.S. patent application Serial No. 09/493,466 filed January 28, 2000 now U.S. Patent No. 6,371,906, which is a divisional of prior U.S. patent application Serial No. 09/334,531 filed June 16, 1999 now U.S. Patent No. 6,364,826, which is a divisional of prior U.S. patent application Serial No. 08/725,371 filed October 3, 1996 now U.S. Patent No. 6,015,378, which is a continuation-in-part of prior U.S. patent application Serial No. 08/531,363 filed September 20, 1995 of Borst et al. entitled METHOD AND APPARATUS FOR TEMPORARILY IMMOBILIZING A LOCAL AREA OF TISSUE now U.S. Patent No. 5,836,311.”

- (2) Claims 1-4, 6, 8-18, 22-26, 28, 30-35, 37, and 39-50 are not anticipated under 35 U.S.C. 102(b) by Vierra 5,749,892.

The Office Action stated claims 1-4, 6, 8-18, 22-26, 28, 30-35, 37, and 39-50 were anticipated by Vierra et al. 5,749,892. Vierra et al. discloses a medical device and a method of using the medical device to immobilize a portion of a stopped heart (see column 11, lines 65-66). The device includes a foot coupled to a shaft 3 at a pivot point 59 and to a rod 43 at a coupling point 49 separated from the pivot point. Axial movement of the rod via a mechanical actuator 69 with respect to the shaft rotates the foot about the pivot point. The actuator is configured to pivot the foot about the transverse axis (see column 4, lines 1-16). The foot comprises members 15 and 17 movable between an open configuration, where the arms are disposed apart in a “V” shape, and a collapsed configuration where the arms are disposed closer together in a substantially parallel configuration (see column 4, lines 23-32). The arms may be biased into the open configuration by a spring 41 (as shown in FIG. 3b), or an actuator (not shown) may be used for moving the arms between the open and collapsed configurations (see column 4, lines 32-35). In the open position, members 15 and 17 are preferably oriented at an angle between 15 and 50 degrees from each other and usually between 35 and 45 degrees (see column 7, lines 23-26). Members 15 and 17 each have a contact surface 27 for engaging tissue (see column 6, lines 58-66) and an inner surface 71 with a plurality of irrigation holes 73 (see column 8, lines 23-26). As

shown in FIG. 2B, contact surface 27 and inner surface 71 of members 15 and 17 are 90 degrees relative to each other. Vierra et al. states that holes 73 are for delivering irrigation fluids to a surgical site or for suctioning fluids from a surgical site (see column 8, lines 22-38). Because holes 73 are for suctioning or delivery fluids to a surgical site, Vierra et al. fails to show or describe holes being positioned along a surface suitable for engaging tissue.

Vierra et al. only discloses members 15 and 17 as being movable relative to each other between two configurations, an open configuration and a closed configuration. Vierra et al. does not disclose a third position. In addition, Vierra et al. only discloses members 15 and 17 being parallel to each other in the closed configuration. In the open configuration, members 15 and 17 are disclosed as being oriented at an angle relative to each other, as opposed to being oriented parallel to each other. Therefore, members 15 and 17 are not disclosed as to move in a parallel relationship relative to each other.

A rejection based on anticipation under 35 U.S.C. 102 requires all of the elements recited in the claims of the invention to be found within the four corners of the cited reference. Claim 1 calls for three positions whereas Vierra only discloses a first configuration where the arms are parallel and a second configuration where the arms are in a V-shape. No third position is disclosed. Claim 1 was amended without prejudice. Amended claim 1 states, “wherein the first and second tissue engaging members are substantially parallel in the first position and at least one of the second and third positions.” Since the arms of Vierra form a V-shape, neither the second nor the third configuration could have parallel arms. Thus the U.S.C. 102(b) rejection should be withdrawn.

Claim 22 was amended without prejudice. Amended independent claim 22 now includes the phrase that the first and second tissue engaging members are substantially parallel to each other in the first and second positions. This element is not disclosed in the Vierra et al. reference, thus the 35 U.S.C. 102(b) rejection should be withdrawn. Claim 23 was amended without prejudice. Amended independent claim 23 and dependent claims 24-26, 28, and 30, all depending from claim 23, include the phrase that a spreader coupled to a first tissue engaging member and a second tissue engaging member is configured to move the first tissue engaging member and the second tissue engaging member among a first position, a second position, and a third position so a selective amount of substantially parallel spreading occurs. This is not disclosed in Vierra et al., thus the 35 U.S.C. 102(b) rejection should be withdrawn. Independent claim 31 includes the phrase that a means for spreading is coupled to a first tissue engaging

member and a second tissue engaging member, the means being configured to move the first tissue engaging member and the second tissue engaging member among a first position, a second position, and a third position so a selective amount of spreading occurs. This feature is not disclosed in Vierra et al., thus the 35 U.S.C. 102(b) rejection should be withdrawn. Independent claim 32 was amended without prejudice. Amended independent claim 32 and dependent claims 33-35, 37, and 39-47, all depending from claim 32, now include the element of controlling the spreading of the first tissue engaging member away from the second tissue engaging member, so a selective amount of substantially uniform spreading occurs. This is not disclosed in Vierra et al., thus the 35 U.S.C. 102(b) rejection should be withdrawn. Independent claim 48 and dependent claims 49 and 50, both depending from claim 48, include the limitation of spreading the first tissue engaging member away from the second tissue engaging member while maintaining the first tissue engaging member substantially parallel to the second tissue engaging member a second distance after the first tissue engaging member has been coupled to the first tissue surface and second tissue engaging member has been coupled to the second tissue surface to place the substantially immobilized tissue under tension within a patient's body. This is not disclosed in Vierra et al., thus the 35 U.S.C. 102(b) rejection should be withdrawn.

- (3) Claims 5, 27, and 36 are not obvious under U.S.C. 103(a) over Vierra et al. 5,749,892 in view of Furnish et al. 5,498,256.

The Office Action stated claims 5, 27, and 36 were rejected under U.S.C. 103(a) over Vierra et al. 5,749,892 in view of Furnish 5,498,256. Vierra et al. discloses a medical device and a method of using the medical device to immobilize a portion of a stopped heart (see column 11, lines 65-66). The device includes a foot coupled to a shaft 3 at a pivot point 59 and to a rod 43 at a coupling point 49 separated from the pivot point. Axial movement of the rod via a mechanical actuator 69 with respect to the shaft rotates the foot about the pivot point. The actuator is configured to pivot the foot about the transverse axis (see column 4, lines 1-16). The foot comprises members 15 and 17 movable between an open configuration, where the arms are disposed apart in a “V” shape, and a collapsed configuration where the arms are disposed closer together in a substantially parallel configuration (see column 4, lines 23-32). The arms may be biased into the open configuration by a spring 41 (as shown in FIG. 3b), or an actuator (not shown) may be used for moving the arms between the open and collapsed configurations (see

column 4, lines 32-35). In the open position, members 15 and 17 are preferably oriented at an angle between 15 and 50 degrees from each other and usually between 35 and 45 degrees (see column 7, lines 23-26).

Vierra et al. discloses members 15 and 17 as being movable relative to each other between two configurations, an open configuration and a closed configuration. Vierra et al. does not disclose a third position. In addition, Vierra et al. only discloses members 15 and 17 being parallel to each other in the closed configuration. In the open configuration, members 15 and 17 are disclosed as being preferably oriented at an angle relative to each other, as opposed to being oriented parallel to each other. Therefore, members 15 and 17 are not disclosed as to move in a parallel relationship to each other.

The Furnish et al. reference discloses a hand lever actuator for a forceps. The hand lever actuator includes an actuator rod coupled to an articulated member of a jaw configuration, wherein movement of the lever causes axial movement of the rod, thereby causing the articulated member of the jaw configuration to pivot between an open position and a closed position. In the open position, the articulated member of the jaw configuration is shown disposed apart in a "V" shape from the fixed member of the jaw configuration (see FIG. 1). Furnish et al. never discloses two members moving relative to each other in a parallel relationship. Further, the members are never disclosed being parallel to each other in an open configuration. In fact, in the open configuration, members 14 and 16 are disclosed as being oriented at an angle relative to each other, as opposed to being oriented parallel to each other.

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. Together the Vierra et al. reference and the Furnish et al. reference do not provide any motivation, suggestion or teaching for an actuator configured to operate a spreader to selectively control the movement of first and second tissue engaging members among a first position, a second position and a third position, wherein the first and second tissue engaging members are substantially parallel to each other in the first, second and third positions as required in dependent claim 5. Therefore, the rejection of claim 5 as being unpatentable over Vierra et al. 5,749,892 in view of Furnish et al. 5,498,256 should be withdrawn. Together the Vierra et al. reference and the Furnish et al. reference do not provide any motivation, suggestion or teachings for a spreader configured to move a first tissue engaging member among a first position, a second position, and a third position, and a second tissue engaging member among a first position, a

second position, and a third position so a selective amount of substantially parallel spreading occurs as required in dependent claim 27. Therefore, the rejection of claim 27 as being unpatentable over Vierra et al. 5,749,892 in view of Furnish et al. 5,498,256 should be withdrawn. Together the Vierra et al. reference and the Furnish et al. reference do not provide any motivation, suggestion or teachings for controlling the spreading of a first tissue engaging member away from a second tissue engaging member, so a selective amount of substantially parallel spreading occurs as required in dependent claim 36. Therefore, the rejection of claim 36 as being unpatentable over Vierra et al. 5,749,892 in view of Furnish et al. 5,498,256 should be withdrawn.

- (4) Claims 7, 29 and 38 are not obvious under U.S.C. 103(a) over Vierra et al. 5,749,892 in view of in view of Garrison et al. 5,613,937.

The Office Action rejected claims 7, 29 and 38 under U.S.C. 103(a) over Vierra et al. 5,749,892 in view of Garrison et al. 5,613,937. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. Together the Vierra et al. reference and the Garrison et al. reference do not provide any motivation, suggestion or teachings for an actuator configured to operate a spreader to selectively control the movement of first and second tissue engaging members among a first position, a second position and a third position, wherein the first and second tissue engaging members are substantially parallel to each other in the first, second and third positions as set forth in dependent claim 7. Therefore, the rejection of claim 7 as being unpatentable over Vierra et al. 5,749,892 in view of Garrison et al. 5,613,937 should be withdrawn. Together the Vierra et al. reference and the Garrison et al. reference do not provide any motivation, suggestion or teachings for a spreader configured to move a first tissue engaging member among a first position, a second position, and a third position, and a second tissue engaging member among a first position, a second position, and a third position so a selective amount of substantially parallel spreading occurs as set forth in dependent claim 29. Therefore, the rejection of claim 29 as being unpatentable over Vierra et al. 5,749,892 in view of Garrison et al. 5,613,937 should be withdrawn. Together the Vierra et al. reference and the Garrison et al. references do not provide any motivation, suggestion or teachings for controlling the spreading of a first tissue engaging member away from a second tissue engaging member, so a selective

amount of substantially parallel spreading occurs as set forth in dependent claim 38. Therefore, the rejection of claim 38 as being unpatentable over Vierra et al. 5,749,892 in view of Garrison et al. 5,613,937 should be withdrawn.

(3) Claims 19-21 are not obvious under U.S.C. 103(a) over Vierra et al. 5,749,892 in view of Hossain et al. 6,063,021.

The Office Action rejected claims 19-21 under U.S.C. 103(a) over Vierra et al. 5,749,892 in view of Hossain et al. 6,063,021. The Hossain et al. reference discloses a device having two members hinged together so that one member can rotate relative to the other member (see column 2, lines 1-7). The members are shaped to form a continuous closed loop having a central opening (see column 2, lines 11-15). The Hossain et al. reference teaches away from two members in parallel arrangement and, instead, claims a benefit for a continuous, closed loop, which can be removed readily after anastomosis of a graft (see column 1, lines 45-53).

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. Together the Vierra et al. reference and the Hossain et al. reference do not provide any motivation, suggestion or teachings for an actuator configured to operate a spreader to selectively control the movement of first and second tissue engaging members among a first position, a second position and a third position, wherein the first and second tissue engaging members are substantially parallel to each other in the first, second and third positions as required in dependent claims 19-21. Therefore, the rejection of claims 19-21 as being unpatentable over Vierra et al. 5,749,892 in view of Hossain et al. 6,063,021 should be withdrawn.

Support for this amendment is clearly found in the application as originally filed. No new matter is presented.

Examination and reconsideration of the application as amended is requested. After amending and adding claims as set forth above, claims 1-68 are pending in the application and are now believed to be in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

This amendment results in a total of sixty-two (62) dependent claims. Please charge the fee of \$324 for the addition of eighteen dependent claims to Deposit Account No. 13-2546.

If the Examiner comes to believe that a telephone conversation may be useful in addressing any remaining open issues in this case, the Examiner is urged to contact the undersigned attorney at 763-391-9661.

A supplemental information disclosure statement accompanies this amendment. Please charge to Deposit Account No. 13-2546 the fee of \$130.00 which is required for the timely submission of the supplemental information disclosure statement.

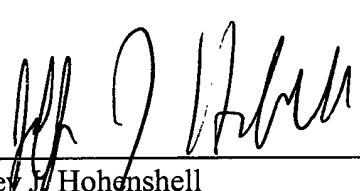
Applicant respectfully petitions the Commissioner for Patents to extend the time for response to the Office Action dated April 21, 2004 for one (1) month from July 21, 2004 to August 23, 2004 (August 21 falls on a Saturday). Please charge the fee provided in:

X 37 C.F.R. 1.17(a)(1) Extension for response within first month

to Deposit Account No. 13-2546. Please also charge any additional fees or credit any overpayment to Deposit Account No. 13-2546.

If any additional fee is required in connection with these papers, please charge such fee to Deposit account No. 13-2546.

Date August 20, 2004

By   
Jeffrey J. Hohenshell  
Reg. No. 34,109  
Senior Patent Attorney  
MEDTRONIC, INC.  
MS LC340  
710 Medtronic Parkway  
Minneapolis, MN 55432  
Tel. 763.391.9661  
Fax. 763.391.9668